

## CLAIMS

1 1. A medical assembly for local delivery of at least one therapeutic substance to an  
2 internal body tissue target area comprising:

3 (a) a catheter having a distal end and a proximal end;

4 (b) a delivery lumen on said catheter, said lumen extending from the distal end of the  
5 catheter to the proximal end of the catheter for the delivery of a therapeutic substance  
6 therethrough; and

7 (c) a first transducer supported by at least a portion of the distal end of the catheter  
8 assembly, said first transducer being supported by said catheter distal end at a preselected number  
9 of anchoring points, wherein an inner surface of the transducer is positioned at a controlled and  
10 preselected distance from an outer surface of the catheter, wherein said distance defines a gap  
11 between said outer surface of the catheter and said inner surface of the transducer.

1 2. The medical assembly of Claim 1, wherein said gap is occupied by a low density  
2 material.

1 3. The medical assembly of Claim 2, wherein said low density material is selected  
2 from the group of ambient air, oxygen, nitrogen, helium, open-cell polymer foam, closed-cell  
3 polymer foam and mixtures thereof.

1 4. The medical assembly of Claim 1, wherein said transducer is tubular.

1 5. The medical assembly of Claim 1, wherein said distance is greater than about 25  
2  $\mu\text{m}$  in length.

1 6. The medical assembly of Claim 1, further comprising perfusion holes disposed at  
2 the proximal end of the catheter.

1 7. The medical assembly of Claim 1, wherein said at least one therapeutic substance  
2 is selected from a group including antineoplastic, antiinflammatory, antiplatelet, anticoagulants,

3 fibrinolytic, thrombin inhibitor, antimitotic, and antiproliferative substances and mixtures  
4 thereof.

1 8. The medical assembly of Claim 1, further comprising:

2 a balloon incorporated at said distal end of the catheter, in fluid communication with said  
3 lumen, said balloon being formed from a membrane having pores, wherein said transducer is  
4 disposed within said balloon.

1 9. The medical assembly of Claim 8, wherein the pores are sized from about 0.3  $\mu\text{m}$   
2 to about 2.5  $\mu\text{m}$ .

1 10. The medical assembly of Claim 1, further comprising:

2 a balloon incorporated at said distal end of the catheter, disposed distally from said  
3 transducer, said balloon being substantially impermeable to said at least one therapeutic  
4 substance.

1 11. The medical assembly of Claim 1, further comprising:

2 a second transducer supported by at least a portion of the distal end of the catheter  
3 assembly, each transducer having a proximal end and a distal end, wherein the distal end of said  
4 first transducer is positioned at a preselected distance from the proximal end of said second  
5 transducer.

1 12. A medical assembly for local delivery of a therapeutic substance to an internal  
2 body tissue target area comprising:

- 3 (a) a catheter having a distal end and a proximal end;  
4 (b) a delivery lumen on said catheter, said lumen extending from the distal end of the  
5 catheter to the proximal end of the catheter for the delivery of a therapeutic substance  
6 therethrough; and

7 (c) a plurality of transducers supported by at least a portion of the distal end of the  
8 catheter assembly, each transducer having a proximal end and a distal end, wherein the distal end  
9 of a transducer is positioned at a preselected distance from the proximal end of an adjacent  
10 transducer.

1 13. The medical assembly of Claim 11, wherein each of said plurality of transducers  
2 are supported by said catheter distal end at a preselected number of anchoring points, wherein an  
3 inner surface of each transducer is positioned at a preselected distance from an outer surface of  
4 the catheter, wherein said distance defines a gap between said outer surface of the catheter and  
5 said inner surface of the transducer.

1 14. A medical assembly for local delivery of a therapeutic substance to an internal  
2 body tissue target area comprising:

3 (a) a catheter having a distal end and a proximal end;

4 (b) a first transducer supported by at least a portion of the distal end of the catheter  
5 assembly, said first transducer being supported by said catheter distal end at a preselected number  
6 of anchoring points, wherein an inner surface of said first transducer is positioned at a  
7 preselected distance from an outer surface of the catheter, and wherein said distance defines a  
8 gap between said outer surface of the catheter and said inner surface of said first transducer;

9 (c) a delivery lumen on said catheter, said lumen extending from the distal end of the  
10 catheter to the proximal end of the catheter for the delivery of a therapeutic substance  
11 therethrough; and

12 (d) a balloon incorporated at said distal end of the catheter, in fluid communication  
13 with said lumen, wherein said first transducer is disposed within said balloon.

1 15. The medical assembly of Claim 14, further comprising:

2  
3 (b) a second transducer supported by at least a portion of the distal end of the catheter  
4 assembly, said first and second transducer each having a proximal end and a distal end, wherein  
5 the distal end of said first transducer is positioned at a preselected distance from the proximal end  
6 of said second transducer.

1           16.     The medical assembly of Claim 15, wherein said transducers are supported by  
2     said catheter assembly at a preselected number of anchoring points, and wherein an inner surface  
3     of each transducer is positioned at a preselected distance from an outer surface of the catheter,  
4     and wherein said distance defines a gap between said outer surface of the catheter and said inner  
5     surface of the transducer.

1           17.     A method for delivering a therapeutic substance to an internal body tissue target  
2     area, the method comprising the acts of:

3           (a)     providing a catheter having a distal end and a proximal end, and further having a  
4     delivery lumen, said delivery lumen extending from the distal end of the catheter to the proximal  
5     end of the catheter for delivery of a therapeutic substance therethrough;

6           (b)     further providing a transducer supported by at least a portion of the distal end of  
7     the catheter assembly, said transducer being supported by said catheter distal end at a preselected  
8     number of anchoring points, wherein an inner surface of the transducer is positioned at a  
9     preselected distance from an outer surface of the catheter, wherein said distance defines a gap  
10    between said outer surface of the catheter and said inner surface of the transducer;

11          (c)     positioning said catheter proximate said internal body tissue;

12          (d)     causing a therapeutic substance to elute from said delivery lumen at the distal end  
13    of the catheter; and

14          (e)     transmitting an electrical signal to said transducer.

1           18.     The method of Claim 17 wherein said therapeutic substance is selected from a  
2     group including antineoplastic, antiinflammatory, antiplatelet, anticoagulants, fibrinolytic,  
3     thrombin inhibitor, antimitotic, and antiproliferative substances and mixtures thereof.

1           19.     A method of treating an internal body tissue with a therapeutic substance  
2     comprising:

3           locally delivering the therapeutic substance in the vicinity of the internal body tissue;

4           generating ultrasonic energy in the vicinity of the internal body tissue;

5           transporting the therapeutic substance, penetrating into the internal body tissue via the

6           ultrasonic energy; and

7 amplifying the applied ultrasonic energy by manipulating an electronic signal driving the  
8 ultrasonic energy generation.

1 20. A method according to Claim 19 further comprising:  
2 amplifying the applied ultrasonic energy by interposing a gap between a catheter for  
3 delivering the therapeutic substance and a transducer for generating the ultrasonic  
4 energy.  
5